Communications & Power Industries

Communications & Power Industries Canada Inc.

K122726

FEB 15 2013

510(k) Summary

Prepared in accordance with 21 CFR 807.92(c)

Date Prepared:	December 19, 2012
Name of Contact Person:	Norm Morikawa
Address:	**Communications & Power Industries Canada Inc.** **45 River Drive, Georgetown, Ontario, L7G 2J4, Canada**
Telephone:	905-877-0161
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Device Trade Name:	**CPI RAD VISION**
Common Name:	Digital Radiography
Classification Name:	Stationary x-ray system (21 CFR 892.1680, Product Code MQB).

Device Description:

The CPI RAD VISION product will provide a user interface to control the digital imaging functions of a radiographic acquisition modality (acquisition, processing, storage, display, and distribution of images from a Solid State X-ray Imager (SSXI)).

The CPI RAD VISION product will also provide either an option on the user interface to control the x-ray generator functions required by a radiographic acquisition modality *or* an optional hardware interface to allow the x-ray generator functions to be controlled by an independent third-party operator console while maintaining synchronization with the digital imaging functions of the product.

CPI RAD VISION is a component of a complete radiographic x-ray system.

Intended Use:

CPI RAD VISION is a digital imaging system intended for the capture and display of radiographic images of human anatomy, as part of a diagnostic x-ray system. It is intended for use in general radiographic examinations and applications. The device is not intended for mammographic, fluoroscopic or angiographic applications.

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Comparison to substantially equivalent devices:

The CPI RAD VISION product is substantially equivalent to the Carestream DRX-1 System (K090318) and the InfiMed i^5 Digital X-ray Imaging System (K093066) since it shares the same intended use, major components, technology, and standard features as these two predicate devices. The following table depicts the comparison characteristics:

	CPI RAD VISION	Carestream DRX-1 System	i^5 Digital X-ray Imaging System
Indicated for use in general radiographic examinations and applications. Not intended for mammographic, fluoroscopic or angiographic applications.	✓	✓	✓
Components / Technology			
High-performance desktop Computer Workstation, large-area LCD Display Monitor, Software	✓	✓	✓
High-resolution Solid State X-ray Imager	✓	✓	✓
Interface for non-integrated configuration, based on a modern circuit board with standard electrical I/O.	✓ *(optional)*	✓	✓ *(optional)*
Medical Grade Isolation Transformer	✓	x	x
Features			
Radiographic image acquisition from Solid State X-ray Imagers.	✓	✓	✓
Enhancement, display, manipulation, review and distribution of radiographic images.	✓	✓	✓
Work list for patient scheduling.	✓	✓	✓
Option for user to manage x-ray settings	✓	x	✓

Performance Testing:

A comprehensive Electrical safety (IEC60601-1:2005) and Electromagnetic compatibility (IEC60601-1-2, Edition 3:2007-03), Software verification (IEC60601-1-4:2000), other performance testing and the acquisition of sample clinical images were performed on CPI RAD VISION product which demonstrated that CPI RAD VISION is safe and effective, and is equivalent to the aforementioned predicates devices.

Conclusion:

The Performance Data demonstrate that CPI RAD VISION product is safe and effective as the predicate devices. Based on the information in this submission, similarity to the predicates devices, and the acquisition of sample clinical images, it is the opinion of CPI (Communications & Power Industries) Canada Inc. that CPI RAD VISION described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

Mr. Norm Morikawa
QA Manager
Communications and Power Industries Canada, Inc.
45 River Drive
GEORGETOWN, ONTARIO, L7G2J4, CANADA

Re: K122726
Trade/Device Name: CPI Rad Vision
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: January 18, 2013
Received: February 1, 2013

Dear Mr. Morikawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

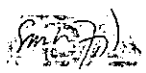
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Diagnostic X-Ray Systems Branch
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122726

Device Name: CPI RAD VISION

Indications For Use: CPI RAD VISION is a digital imaging system intended for the capture and display of radiographic images of human anatomy, as part of a diagnostic x-ray system. It is intended for use in general radiographic examinations and applications. The device is not intended for mammographic, fluoroscopic or angiographic applications.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health